

OCT 7 - 2004

510(K) SUMMARY

K042514

Name of Firm: Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, MA 01104

510(k) Contact: Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance

Trade Name: Blackstone™ Modular Pedicle Screw System

Common Name: Rod and Screw Spinal Instrumentation

**Device Product Code
& Classification:** MNI - 888.3070 – Pedicle Screw Spinal System
KWQ - 888.3060 - Spinal Intervertebral Body Fixation Orthosis
MNH – 888.3070 Spondylolisthesis Spinal Fixation Device System

Substantially Equivalent Devices:

Blackstone™ Spinal Fixation System (K994217)
Blackstone™ SFS 4.5mm Multi-Axial Screws (K020674)
Blackstone™ SFS Modification to Multi-Axial Screws (K023498)
Blackstone™ SFS 4.5mm Mono-Axial Screws (K013558)
Blackstone™ SFS Lateral Offset (K030581)

Device Description:

The Blackstone™ Modular Pedicle Screw System is comprised of non-sterile, single use, titanium alloy components. The Blackstone Modular Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spine and allows a surgeon to build a spinal implant construct. This system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space.

Intended Use / Indications for Use:

The Blackstone Modular Pedicle Screw System is intended for non-cervical use in the spine.

The Blackstone Modular Pedicle Screw System, when used for pedicle screw fixation, is intended only for patients:

- a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
- b) Who are receiving fusion using autogenous bone graft only;
- c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
- d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Modular Pedicle Screw System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

- a) Degenerative spondylolisthesis with objective evidence of neurological impairment;
- b) Fracture;
- c) Dislocation;
- d) Scoliosis;
- e) Kyphosis;
- f) Spinal tumor;
- g) Failed previous fusion (pseudarthrosis).

The Blackstone Modular Pedicle Screw System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis and/or lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation);
- h) Failed previous fusion.

The Blackstone Modular Pedicle Screw System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis and/or lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation);
- h) Failed previous fusion.

BASIS OF SUBSTANTIAL EQUIVALENCE:

By its very nature, the Blackstone™ Modular Pedicle Screw System is substantially equivalent to the Blackstone™ Spinal Fixation System (K994217), which has been cleared by FDA for use in spinal fusion surgery.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance
Blackstone Medical Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K042514

Trade/Device Name: Blackstone™ Modular Pedicle Screw System
Regulation Number: 21 CFR 888.3060, 21 CFR 888.3070
Regulation Name: Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, KWQ, MNI
Dated: September 12, 2004
Received: September 16, 2004

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

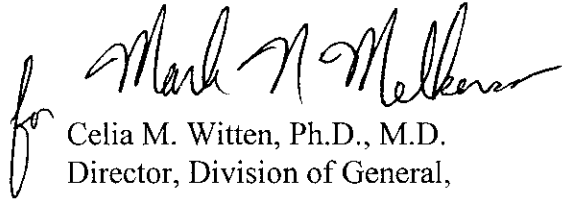
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Dean E. Ciporkin

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark N. Melker

Celia M. Witten, Ph.D., M.D.
Director, Division of General,
Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042514

Device Name: Blackstone™ Modular Pedicle Screw System

Indications for Use:

The Blackstone Modular Pedicle Screw System is intended for non-cervical use in the spine.

The Blackstone Modular Pedicle Screw System, when used for pedicle screw fixation, is intended only for patients:

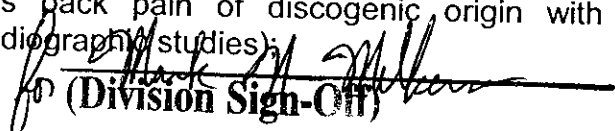
- a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
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- f) Spinal tumor;
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The Blackstone Modular Pedicle Screw System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

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- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation).
- h) Failed previous fusion.


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042514

The Blackstone Modular Pedicle Screw System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

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- h) Failed previous fusion.

Prescription Use X
(Part 21 CFR 801 Subpart D)

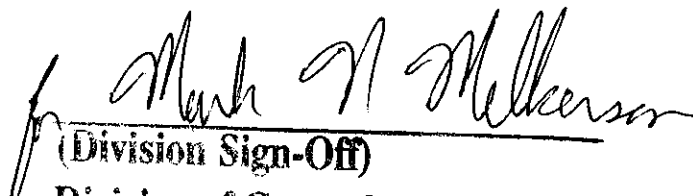
AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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